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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,611	05/11/2006	Hyoung-Joon Jin	TUV-031.01	6317

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EXAMINER	
MONDESI, ROBERT B	

ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/533,611	JIN ET AL.	
	Examiner	Art Unit	
	ROBERT B. MONDESI	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *January 14, 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *1-15 and 24-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *April 29, 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/03/07 and 3/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Please vacate the notice of noncompliant amendment, mailed March 26, 2008 in favor of the instant Office Action.

Response to restriction requirement

Applicants' election with traverse of Invention of Group II, **claims 16-23** and the further election of silk as the fibrous protein in amendment, filed January 14, 2008 is acknowledged. The traversal is on the ground(s) that the search and examination of an entire application can be made without burden. This is not found persuasive because the search and examination of the elected invention of Group II will not reveal references that are relevant to the claimed invention of Group V. The elected invention of Group II is drawn to a method of obtaining predominantly one enantiomer from a mixture of enantiomers, comprising the steps of: a. contacting an aqueous fibrous protein solution with a solvent that is not miscible with water; b. allowing the solution in contact with the solvent to age at about room temperature or under conditions preventing evaporation or both; c. allowing the enantiomers of the mixture to diffuse selectively into the resulting fibrous protein smectic hydrogel in solution; d. removing the smectic hydrogel from the solution; e. rinsing predominantly a first enantiomer from the surface of the smectic hydrogel; and f. extracting predominantly a second enantiomer from the interior of the smectic hydrogel, whereas the invention of Group V is drawn to method of obtaining predominantly one enantiomer from a mixture of enantiomers of a chiral molecule, the method comprising: a) contacting the mixture of enantiomers with a chiral composition comprising a liquid crystalline ordered solid having a nanoscale

multilayered structure, wherein each layer comprises a molecularly oriented fibrous protein, and wherein the layers define an interlayer region having nanoscale chiral pores or channels; and b) isolating predominantly one enantiomer within the chiral composition. The preamble of these methods might create an appearance that they are distinct but a closer look at the active steps involved in the invention clearly demonstrate that there search of the invention of Group V would not be related to the search of the invention of Group II and therefore would create a burden on the examiner and the Patent Office.

Therefore the requirement is still deemed proper and is made FINAL. **Claims 31-48** are new and have been added. **Claims 1-48** are pending in this application. **Claims 1-15** are withdrawn from further consideration because these Claims are drawn to non-elected inventions. **Claims 16-23** are currently under examination.

Priority

The current application filed on May 11, 2006 is a 371 of PCT/US03/34684 filed on 10/31/2003 which claims benefit of 60/423,046 filed on 11/01/2002.

Preliminary Amendment

The preliminary amendment filed April 29, 200 5 has been entered.

Drawings

The drawings are objected to because Figures 30 contain text that appear to be description of the drawing and not related to an office acceptable legend under 37 CFR 1.84(o), such description belongs in the Brief Description of the Drawings in the specification of the application (The mentioned text appears on the right side of the

Fig.). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

The IDS filed December 3, 2007 and March 3, 2006 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Specification

This application contains sequence disclosures at page 7, lines 12-14, lines 20-21, 29-30; that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 C.F.R. § 1.821(a((1) and (a)(2). However, the fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below:

Nucleic acid sequences of 10 or more nucleotides and amino acid sequences of 4 or more residues need to be designated with a sequence identifier. Wherein attention is directed to paragraph(s) §1.82 (c) and (e). Although an examination of this application on the merits can proceed without prior compliance, compliance with the Sequence Rules is required for the response to this Office action to be complete.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 18-32 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of obtaining predominantly one enantiomer from a mixture of enantiomers, comprising the steps of: a. contacting an aqueous fibrous protein solution, **wherein the fibrous protein is selected form a group consisting of silk, collagens, keratins, actins, chorions, and seroins** with a solvent that is not miscible with water, **wherein the solvent is selected form a group consisting of hexane, chloroform and iso-amyl alcohol**; b. allowing the solution in contact with the solvent to age at about room temperature or under conditions preventing evaporation or both; c. allowing the enantiomers of the mixture to diffuse selectively into the resulting fibrous protein smectic hydrogel in solution; d. removing the smectic hydrogel from the solution; e. rinsing predominantly a first enantiomer from the surface of the smectic hydrogel; and f. extracting predominantly a second enantiomer from the interior of the smectic hydrogel, does not reasonably provide enablement for a

method of obtaining predominantly one enantiomer from a mixture of enantiomers, comprising the steps of: a. contacting an aqueous fibrous protein solution **wherein the fibrous protein is any fibrous protein** with a solvent that is not miscible with water, **wherein the solvent is any solvent that is not immiscible with water**; b. allowing the solution in contact with the solvent to age at about room temperature or under conditions preventing evaporation or both; c. allowing the enantiomers of the mixture to diffuse selectively into the resulting fibrous protein smectic hydrogel in solution; d. removing the smectic hydrogel from the solution; e. rinsing predominantly a first enantiomer from the surface of the smectic hydrogel; and f. extracting predominantly a second enantiomer from the interior of the smectic hydrogel. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir.1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be

considered in determining whether undue experimentation is required include: (1) the breadth of the claims, (2) the nature of the invention, (3) the state of the prior art, (4) the predictability or unpredictability of the art, (5) the relative skill of those in the art, (6) the amount or direction or guidance presented, (7) the presence or absence of working examples, and (8) the quantity of experimentation necessary. Although the quantity of experimentation alone is not dispositive in a determination of whether the required experimentation is undue, this factor does play a central role. For example, a very limited quantity of experimentation may be undue in a fledgling art that is unpredictable where no guidance or working examples are provided in the specification and prior art, whereas the same amount of experimentation may not be undue when viewed in light of some guidance or a working example or the experimentation required is in a predictable established art. Conversely, a large quantity of experimentation would require a correspondingly greater quantum of guidance, predictability and skill in the art to overcome classification as undue experimentation. In Wands, the determination that undue experimentation was not required to make the claimed invention was based primarily on the nature of the art, and the probability that the required experimentation would result in successfully obtaining the claimed invention. (Wands, 8 USPQ2d 1406). Thus, a combination of factors which, when viewed together, would provide an artisan of ordinary skill in the art with an expectation of successfully obtaining the claimed invention with additional experimentation would preclude the classification of that experimentation as undue. A combination of Wands factors, which provide a very low

likelihood of successfully obtaining the claimed invention with additional experimentation, however, would render the additional experimentation undue.

1-2 .Breadth of the claims and the nature of the invention..

In regards to the method of the invention and the breadth of the claims the broadest interpretation that applies a is a method of obtaining predominantly one enantiomer from a mixture of enantiomers, comprising the steps of: a. contacting an aqueous fibrous protein solution **wherein the fibrous protein is any fibrous protein** with a solvent that is not miscible with water, **wherein the solvent is any solvent that is not immiscible with water**; b. allowing the solution in contact with the solvent to age at about room temperature or under conditions preventing evaporation or both; c. allowing the enantiomers of the mixture to diffuse selectively into the resulting fibrous protein smectic hydrogel in solution; d. removing the smectic hydrogel from the solution; e. rinsing predominantly a first enantiomer from the surface of the smectic hydrogel; and f. extracting predominantly a second enantiomer from the interior of the smectic hydrogel.

3-4. The state of prior art and the level of predictability in the art.

The level of predictability is low in art. The prior art is silent with regards to a method of obtaining predominantly one enantiomer from a mixture of enantiomers, comprising the steps of: a. contacting an aqueous fibrous protein solution **wherein the fibrous protein is any fibrous protein** with a solvent that is not miscible with water, **wherein the solvent is any solvent that is not immiscible with water**; b. allowing the solution in contact with the solvent to age at about room temperature or under

conditions preventing evaporation or both; c. allowing the enantiomers of the mixture to diffuse selectively into the resulting fibrous protein smectic hydrogel in solution; d. removing the smectic hydrogel from the solution; e. rinsing predominantly a first enantiomer from the surface of the smectic hydrogel; and f. extracting predominantly a second enantiomer from the interior of the smectic hydrogel.

5. The relative skill in the art.

The relative skill in the art as it relates to the method of the invention is characterized by that of a M.D. or Ph. D. level individual.

6-7. The amount of guidance present and the existence of working examples.

The applicant has not provided sufficient guidance for a method of obtaining predominantly one enantiomer from a mixture of enantiomers, comprising the steps of: a. contacting an aqueous fibrous protein solution **wherein the fibrous protein is any fibrous protein** with a solvent that is not miscible with water, **wherein the solvent is any solvent that is not immiscible with water**; b. allowing the solution in contact with the solvent to age at about room temperature or under conditions preventing evaporation or both; c. allowing the enantiomers of the mixture to diffuse selectively into the resulting fibrous protein smectic hydrogel in solution; d. removing the smectic hydrogel from the solution; e. rinsing predominantly a first enantiomer from the surface of the smectic hydrogel; and f. extracting predominantly a second enantiomer from the interior of the smectic hydrogel.

However the specification in pages 27-29 provides examples and guidence for a a method of obtaining predominantly one enantiomer from a mixture of enantiomers,

comprising the steps of: a. contacting an aqueous fibrous protein solution, **wherein the fibrous protein is selected form a group consisting of silk, collagens, keratins, actins, chorions, and seroins** with a solvent that is not miscible with water, **wherein the solvent is selected form a group consisting of hexane, chloroform and iso-amyl alcohol**; b. allowing the solution in contact with the solvent to age at about room temperature or under conditions preventing evaporation or both; c. allowing the enantiomers of the mixture to diffuse selectively into the resulting fibrous protein smectic hydrogel in solution; d. removing the smectic hydrogel from the solution; e. rinsing predominantly a first enantiomer from the surface of the smectic hydrogel; and f. extracting predominantly a second enantiomer from the interior of the smectic hydrogel

8. The quantity of experimentation necessary.

The amount of experimentation that is required is undue: while a method of obtaining predominantly one enantiomer from a mixture of enantiomers, comprising the steps of: a. contacting an aqueous fibrous protein solution, **wherein the fibrous protein is selected form a group consisting of silk, collagens, keratins, actins, chorions, and seroins** with a solvent that is not miscible with water, **wherein the solvent is selected form a group consisting of hexane, chloroform and iso-amyl alcohol**; b. allowing the solution in contact with the solvent to age at about room temperature or under conditions preventing evaporation or both; c. allowing the enantiomers of the mixture to diffuse selectively into the resulting fibrous protein smectic hydrogel in solution; d. removing the smectic hydrogel from the solution; e. rinsing predominantly a first enantiomer from the surface of the smectic hydrogel; and f.

extracting predominantly a second enantiomer from the interior of the smectic hydrogel might be considered routine, a method of obtaining predominantly one enantiomer from a mixture of enantiomers, comprising the steps of: a. contacting an aqueous fibrous protein solution **wherein the fibrous protein is any fibrous protein** with a solvent that is not miscible with water, **wherein the solvent is any solvent that is not immiscible with water**; b. allowing the solution in contact with the solvent to age at about room temperature or under conditions preventing evaporation or both; c. allowing the enantiomers of the mixture to diffuse selectively into the resulting fibrous protein smectic hydrogel in solution; d. removing the smectic hydrogel from the solution; e. rinsing predominantly a first enantiomer from the surface of the smectic hydrogel; and f. extracting predominantly a second enantiomer from the interior of the smectic hydrogel is not routine and requires more experimentation. Therefore, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability as evidenced by the prior art, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention.

It must be noted that the issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The Applicants make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "... scope of claims must bear a reasonable correlation to scope of enablement provided

by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQZd at 1404 (Fed. Cir. 1988). Therefore, for the instant specification to be enabling, it needs to provide direction/guidance regarding an acceptable number of different fibrous proteins and solvents.

Absent sufficient guidance/direction one of skill in the art would not be able to practice the claimed invention commensurate in scope with the claims. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and insufficient working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to test all the different type fibrous proteins and solvents encompassed by the claimed invention would constitute undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT B. MONDESI whose telephone number is (571)272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashed Nashaat can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/
Primary Examiner
Art Unit 1652
April 22, 2008

RBM